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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,969	03/22/2005	Marlene Michelle Dressman	4-32459A	6140

75074 7590 01/09/2008  
NOVARTIS INSTITUTES FOR BIOMEDICAL RESEARCH, INC.  
400 TECHNOLOGY SQUARE  
CAMBRIDGE, MA 02139

EXAMINER
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WHALEY, PABLO S

ART UNIT	PAPER NUMBER
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1631

MAIL DATE	DELIVERY MODE
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01/09/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<p align="center"><b>Office Action Summary</b></p>	<p><b>Application No.</b></p> <p align="center">10/510,969</p>	<p><b>Applicant(s)</b></p> <p align="center">DRESSMAN ET AL.</p>	
	<p><b>Examiner</b></p> <p align="center">Pablo Whaley</p>	<p><b>Art Unit</b></p> <p align="center">1631</p>	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 October 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-69 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-69 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Lack of Unity*

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

**Group I:** Claims 1-5, 10-36, and 42-58 drawn to a method and kit to predict which patients will respond to tyrosine kinase inhibitor, classified in class 702, subclass 019.

**Group II:** Claims 6-9, 37-41, and 59-69 drawn to a method and kit for determining the responsiveness of a patient with a tyrosine inhibitor drug responsive disorder to treatment, classified in class 702, subclass 019.

And it considers that the International Application does not comply with the requirements of unity of invention (Rules 13.1, 13.2, and 13.3) for the reasons listed below:

The inventions listed as Groups I and II do not relate to a single-inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking Group I and II appears to be that they are all directed to an information processing method for predicting patient response to tyrosine kinase inhibitors.

However, Beham-Schmidt et al. (Blood, 1 January 2002, Vol. 99, No. 1, pp. 381-383) teach a method for treating chronic leukemia using tyrosine kinase inhibitors. Therefore, the lack of unity is present because the linking technical feature is not a "special technical feature" as defined by PCT Rule 13.2

Further, the inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Each of the Groups I and II claim a distinct and separate method as follows. The methods do not share a special technical feature because each method contains specific and unique method steps which are not shared by each of the other methods and each method has a unique and distinct outcome.

The special technical feature of Group I is considered to be determining expression levels, compares gene profiles, determines correlation coefficients, and determining that the patient will have complete cytogenetic response to the tyrosine inhibitor based on a correlation coefficient.

The special technical feature of Group II is considered to be determining the identity of nucleotide pairs and different polymorphic positions in different genes, and assigning the individual to a responder group. Therefore, each Group requires a distinct mode of operation that is not required by the other.

Thus, Groups I and II do not share a corresponding special technical feature. Accordingly, Groups I and II are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

1. In addition, each Group detailed above reads on distinct Groups drawn to different sequences. Group I requires a combination of reporter genes, as recited in claim 1 and listed in Tables 12A and 12B. Applicant is required to elect a single combination of reporter genes from those listed in Tables 12A and 12B for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Group II contains different species of nucleotide positions, as recited in claims 6, 7, 8, 37, 38, and 39. Applicant is required to elect a single polymorphism position from those listed in claims 6, 7, 8, 37, 38, and 39 for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

The sequences are distinct because they are unrelated sequences that do not share a common property or activity, and do not have a common structural element that is essential to a common property or activity (see the PCT International Search and Preliminary Examination Guidelines (accessible at [www.wipo.int/pct/en/texts/gdlines.htm](http://www.wipo.int/pct/en/texts/gdlines.htm)) at paragraphs 10.17 and 10.52-10.59), and a further lack of unity is applied to each Group. The Applicants must further elect one sequence for examination in the elected Group detailed above. Payment of fees for an additional invention will entitle the Applicants to examination of one additional sequence.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pablo Whaley whose telephone number is (571)272-4425. The examiner can normally be reached on 9:30am - 6pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached at 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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